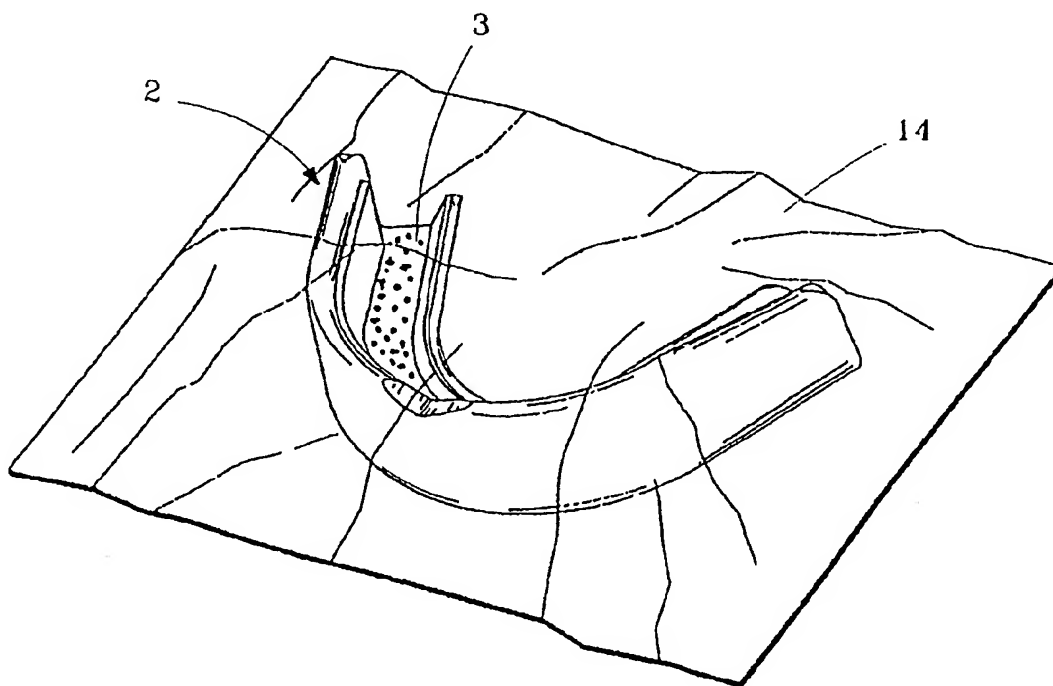




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(54) Title: DEVICE AND METHOD FOR TREATMENT OF DENTITION**(57) Abstract**

A device (2) composed of a non-porous polymeric material having a trough for immersing the teeth of the dental arch, the dental appliance (2) being adaptable to fit a range of variously sized dental arches, which may further include a buffer region (7), and method for applying bleaching, antioxidant, and other dental and medicinal agents (3) to the dental arches and periodontal tissue.

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Description

DEVICE AND METHOD FOR TREATMENT OF DENTITION

5 This is a continuation in part of Application Serial No. 07/980,635 for Apparatus and Method For Lightening Teeth, which was filed on November 24, 1992.

Field of the Invention

10 The apparatus and method of this invention relate to dental treatments.

Background of the Invention

15 Recently, home bleaching has been introduced into the dental health care market for the management of stained teeth. Home bleaching is a technique utilizing weak oxidizing agents such as 6 to 15 percent carbamide peroxide or other peroxy compound which are delivered to the dental arch by the patient using a rigid dental appliance which is custom fabricated by a dentist or dental laboratory. Protocols outlined by dental professionals for the treatment of stained teeth employing the home bleaching technique generally recommend that the patient wear a rigid custom dental appliance for periods of up to 120 minutes per day usually over the course of several weeks, totaling between 20 to 40 hours of home bleaching time.

20 All currently available bleaching agents are either viscous liquids or gels. Bleaching agents are commercially available and packaged in separate dispensing containers such as bottles, syringes, and tubes. The bleaching agent is self-administered by the patient, who dispenses an estimated quantity of bleaching agent to the rigid custom dental appliance.

25 The exact origin of the home bleaching procedure is unclear. The earliest reports of this technique occurred in the mid-1960's when two dentists in Arkansas reported Glyoxide™, which is commercially available from Marion Merrel Dow, Inc. Glyoxide is an agent used in a custom dental appliance, or dental splint, for soft tissue wound healing, resulted in the desirable side effect of whitening teeth. Glyoxide™ is an over-the-counter preparation containing 10% carbamide peroxide in glycerine. These dentists switched to Proxigel™, which is commercially available from Reed & Carnrick Pharmacy after its introduction into the over-the-counter market in 1972. Proxigel™ is a combination of water, glycerine, Carbopol™ (thickening agent) and 10% carbamide peroxide.

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The first report of the home bleaching procedure was published in 1989, when Haywood and Heymann reported successful bleaching using Proxigel™ in a custom fabricated dental appliance to be worn at night. In the Haywood and Heymann procedure, the bleaching agent was placed in a soft plastic, vacuum formed dental appliance for an average of 7.5 hours per night for 2 to 5 weeks. Also, in 1989, White and Brite™, which is marketed by Omni International, became the first commercially available dental bleaching agent specifically for whitening teeth. White and Brite™ is a preparation containing 10% carbamide peroxide in glycerine which is sold exclusively to dentists and sold in conjunction with custom-fitted or prescription dental appliances. Since its introduction into the dental health care market, over 20 companies have marketed similar products.

The aforementioned home bleaching techniques require two dental office visits and the fabrication of a rigid custom dental appliance. During the first office visit, impressions of the dental arches are taken, from which rigid custom-fitted dental appliances are fabricated. The use of thermoplastic films are recommended for the fabrication of rigid custom dental appliances which function to carry and deliver various home bleaching agents to the dental arches. Thermoplastic films are sold as rigid or semi-rigid sheeting and are available in various sizes and thicknesses. Some manufacturers also offer laminations of porous foams or low modulus plastics to rigid thermoplastic films.

Fabrication of rigid custom dental appliances to stone models of the dental arches necessitates heating and vacuum forming a rigid thermoplastic sheet to the stone models of a patient's dental arches. The excess sheeting is subsequently removed and the resulting rigid custom dental appliance polished and provided to the dentist for fitting to the patient's dental arches.

Dentists have traditionally utilized one of three types of dental appliances for bleaching teeth. The first type is a rigid appliance which is fitted precisely to the patient's dental arches.

A second type of rigid custom dental appliance frequently practiced by dentists is the delivery of home bleaching agents in an "oversized" rigid custom dental appliance. The dental laboratory fabrication technique for the oversized rigid dental appliance involves augmenting the facial surfaces of the teeth on the stone models with materials such as die spacer or light cured acrylics. Next, thermoplastic sheeting is heated and subsequently vacuum formed around the augmented stone models of the dental arch. The net effect of this method results in an "oversized" rigid custom dental appliance.

A third type of rigid custom dental appliance, which is used with less frequency, is a rigid bilaminated custom dental appliance fabricated from laminations of

materials, ranging from soft porous foams to rigid, non-porous films. The non-porous, rigid thermoplastic shells of these bilaminated dental appliances encase and support an internal layer of soft porous foam.

After consultation with the dentist and fabrication of the aforementioned dental appliance, a teeth whitening procedure utilizing the dental appliance is practiced by the patient, who then typically applies the bleaching agent daily. The patient dispenses the home bleaching agent into the rigid custom dental appliance and then places the appliance over the dental arch. Generally, the recommended treatment period ranges from 30 to 120 minutes per day. At the end of the treatment period, the dental appliance is removed, cleaned with water to remove any remaining bleaching agent, and then stored until the next application.

Unfortunately, there exist many problems with obtaining rigid custom-fabricated dental appliances. Such problems include the time and expense of making dental impressions and dental laboratory work, two office visits, and possibly reshaping poorly fitted appliances.

There exist additional drawbacks with custom bilaminated dental devices, including occlusion and retention of bleaching agent. Furthermore, cleaning and maintenance of the foam-lined dental appliance is difficult, due to its high surface area and pore volume.

Yet further problems of oversized rigid custom dental appliance, including, but not limited to, occlusion, increased fabrication time and cost, irritation and the lip of the appliance contacting the gingival region, and decreased retention to the bleaching agent within the target area.

Such problems triggered the development of a fourth and final type of treatment regimen employed to deliver home bleaching. That regimen replaces rigid custom dental appliances with individually packaged disposable U-shaped soft foam trays saturated with a premeasured quantity of bleaching agent. Such a device is commercially available from Cadco Dental Products in Oxnard, California under the tradename VitalWhite™. Recommended treatment protocol described in the product's package insert instructs the patient to fit the device around his or her teeth and to keep the tray in position for sixty minutes after which time it is removed and discarded. Cadco suggests that fourteen sixty minute applications be delivered in a two week period.

Unfortunately, however, foam appliances used in home bleaching systems such as that provided by Cadco have proven to be replete with their own problems. The porous foam tray of such systems is bulky, lacks adequate structural rigidity to fit securely over the dental arches, and causes excessive salivation.

Such foam appliances fail to direct and confine the application of home bleaching agents on the surfaces of a patient's teeth, which is critical to the safety and efficacy of any dental appliance, or other medical device used in or on the human body. Furthermore, the surfaces of such foam devices, which are saturated with bleaching agent, are open and exposed to the oral cavity, and allow the elution of large quantities of bleaching agent from the device, enter the oral cavity, and be ingested by the patient. In addition, because of the discomfort associated with the moisture buildup resulting from foaming of the bleaching agent and salivation, patient compliance and acceptance is low.

Further drawbacks attendant to prior art teeth bleaching methods include hypersensitive reactions, nausea and other untoward side effects resulting. Such side effects may result from application of strong concentrations of bleaching agent to the dental arches of a patient who is unaccustomed to teeth bleaching. To date, no medicinal agents have been derived to alleviate or attenuate such and other contraindications.

Nor have compositions been derived to generally improve the condition of the teeth and mouth, regardless of whether the dentition have been subject to whitening or other of any other dental procedure.

Thus, there exist many problems with devices for delivering home bleaching agents which are presently available. Conventional rigid, custom-fabricated dental appliances require time-consuming and expensive dentist office visits, dental laboratory tests and fitting of each patient's dentition. Furthermore, any changes in the surface of the patient's teeth, such as fillings, crowns, and other accidental or therapeutic alterations of the dentition, would affect the fit of the rigid custom dental appliance and warrant repeating the entire fabrication procedure. Refabrication of the splint may also be required in the event of subsequent rebleaching.

Still further drawbacks with systems utilizing known systems for treatment of dental arches result improper dispensation of agent into dental appliances, particularly when the agent is dispensed by patients who are typically inexperienced and unaware of the importance of precision and infection control when self-administering such agents. As a result of such improper dispensing techniques, bleaching or other medicinal agent is often overfilled, spilled or incorrectly measured. Lack of aseptic technique increases the risk of contaminating the bleaching or other dental agent into an appliance. Patients who are self administering bleaching or other medicinal agents often fail to provide the careful maintenance, cleaning, and storage which is necessary for a rigid custom dental appliance to perform adequately throughout its entire service life.

Yet further problems result from patients' frequent dispersion of excessive bleaching or other medicinal agent into the dental appliance which is subsequently

displaced from the appliance into the oral cavity and spilled into the mouth, ingested and introduced into the digestive system. Ingestion of significant amounts of bleaching agent may cause the user great discomfort and hypersensitive reactions. The resulting application of excessive bleaching agent and leakage of bleaching agent from the dental carriers or retainers may also cause gingival irritation, burning, edema, nausea and other allergic reactions. A patient may be thus subjected to excessive quantities of bleaching agent, particularly after the multiple treatments typically required to attain acceptable clinical results.

Moreover, the sponge-like permeability of disposable foam trays merely exacerbated problems of systems utilizing custom dental appliances, including poor retention or confinement of the bleaching agent to the target area and ingestion of the agent. These problems are not exhaustive but are mere examples of difficulties encountered with present devices. Therefore, it is apparent that there is a need for substantial improvement in dental treatments involving application of bleach or other medicinal agents to a patient's dentition and periodontal tissue.

Summary of the Invention

The above and other drawbacks of the prior art are addressed by the present device and method for effecting delivery of bleaching or other medicinal agents to a user's dental arches and periodontal tissue. The present invention provides a dental device for the treatment of dental arches and periodontal tissue, comprising a prefabricated dental appliance composed of a non-porous polymeric material having a trough for immersing the teeth of the dental arch, the dental appliance being adaptable to fit a range of variously sized dental arches, and a premeasured amount of bleaching and/or other medicinal agent predisposed within the trough of the disposable dental appliance. According to the present invention, the dental device of the present invention may be packaged in a kit such that the predisposed bleaching or other medicinal agent is sealed in a package surrounding the appliance or sealed in the trough of the dental appliance. Alternatively, the medicinal agent may be packaged in a separate container located adjacent to the trough orifice, the container being sealed in a manner whereby the medicinal agent is capable of being directly expelled into the trough of dental appliance when the seal is opened.

The present system for treatment of the dental arches and periodontal tissue thus provides for application of a medicinal agent in one simple step, after the appliance is removed from the package. The simple administration of bleaching agent according to the present invention both optimizes hygiene and minimizes the risk of

untoward side effects, by preventing spillage and contamination of the agent. The utilization of premeasured and predispensed medicinal agent further provides a virtually foolproof method for accurate delivery advantages of bleaching or other agents to dentition and periodontal tissue.

5 As used herein, a prefabricated dental appliance is a dental appliance which is subject to mass production of a universal size or sizes adaptable to fit a range of variably sized dental arches. Conversely, the prefabricated dental appliance of the present invention is not custom fitted to individual dental arches.

10 As used herein, a medicinal agent is any composition containing a pharmaceutical, bleaching or other dental agent, a nutrition supplement, or other biocompatible compound capable of improving the condition of or minimizing untoward side effects of bleaching or other dental treatments on the dental arches and periodontal tissue. Such compounds may include, but are not limited to, dental bleaching agents, such as carbamide peroxide, antioxidants, such as vitamin E, healing agents such as aloe vera, 15 surfactants for coating the surface of the teeth with a whitener, such as poloaxmer, anti-caries agents such as fluoride, or even dental scrubs which can be brushed to polish the teeth after the treatment of the present invention has been applied.

20 One embodiment of the present invention features a dental appliance wherein a first strip of open cell foam is affixed along the anterior inner wall of the dental appliance and a second strip of open cell foam is affixed along the rear inner wall of the dental appliance such that a reservoir cavity for containment of the medicinal agent is formed along the bottom of the trough of the dental appliance.

25 Alternatively, a strip of open cell foam may be affixed along the anterior inner wall of the trough of the dental appliance for contacting the anterior portion of the dental arch subject to treatment. Medicinal agent may be predispensed within the open cell foam affixed to the inner wall or walls of the dental appliance according to the present invention or be predispensed within a separate container which is located within or adjacent to the trough of the dental appliance.

30 In such and other embodiments of the present invention, the anterior inner wall surface of the trough can be recessed along substantially the entire anterior inner wall surface of the trough of the dental appliance so as to form a treatment chamber for contacting the anterior surface of the teeth subject to treatment.

35 A still further feature of the present invention includes a buffer region in the area around the periodontal tissue surrounding the teeth subject to treatment, the buffer region containing material to prevent the periodontal tissue from coming into contact with the active bleaching agent. The buffer region preferably contains a chemical compound

capable of stabilizing or otherwise minimizing the potentially untoward side effects of the active bleaching agent. In another embodiment of the invention, the buffer region contains an adhesive, such as zinc oxide eugenol.

Yet another feature of the present invention includes application of other
5 medicinal agents capable of imparting potential therapeutic effect or to minimize the risk of bleaching or other agents of having potentially untoward side effects upon the teeth and surrounding tissue. As previously defined, medicinal agents may include antioxidants such as vitamin E, surfactants for coating the surface of the teeth with a whitener such as poloaxmer, healing agents such as aloe vera, anti-caries agents such as fluoride, or even
10 dental scrubs which can be brushed to polish the teeth after the treatment of the present invention has been applied.

An important advantage provided by the prefabricated dental appliance of the present invention includes elimination of the need for dental impressions and fabrication of a custom dental appliance, as it is designed to fit a range of variously sized
15 dental arches. The appliance thus need not be prescription fitted or custom made, and thus may purchased over the counter. The capability for utilizing and maintaining sterile packaging and single use of the present invention may further minimize drawbacks attendant to bacterial contamination and cleaning.

The device and method of the present invention provides the further benefit
20 of facilitating localized application of medicinal compounds, such as bleaching agents, which may be associated with untoward side effects, as discussed above. For instance, targeting the treatment surface on just the anterior surface of the teeth when applying bleaching procedures to the visible anterior surface of the teeth provides the advantage of requiring less bleaching agent and minimizing the risk of hypersensitive, or other untoward
25 side effects.

A method for treating dental arches and surrounding tissue according to the present invention includes the steps of selecting a prefabricated dental appliance composed of a non-porous polymeric material adaptable to fit a range of variously sized dental arches having a trough for immersing the teeth and periodontal tissue of the dental
30 arch which contains a medicinal agent, and applying the dental appliance so as to immerse a user's dental arches in the medicinal agent.

A further feature of the method according to the present invention includes a treatment including application of an antioxidant to the dental arches and surrounding tissue. As with the device of the present invention, such an antioxidant is preferably
35 vitamin E. The method of the present invention may further include application of aloe

vera to the dental arches and surrounding tissue. Such medicinal agents can be applied together with or separately from bleaching or other dental treatments.

A further method of the present invention includes a lightening treatment regiment wherein progressively higher concentrations of bleaching agent are applied to the dental arches. The method of treatment may include administering: (1) between 2 and 10 applications of bleaching agent comprised of between about 5% and about 15%, and preferably about 10%, carbamide peroxide or other bleaching agent; (2) between 2 and 10 applications of bleaching agent comprised of between about 8% and about 18%, and preferably about 12.5%, carbamide peroxide or other bleaching agent; and (3) between 2 and 10 applications of bleaching agent comprised of between about 10% and about 20%, and preferably about 15%, carbamide peroxide or other bleaching agent. A further feature of this embodiment of the method according to the present invention, as with other embodiments discussed above, includes application of other medicinal agents, as defined above, with one or more bleaching application treatments.

Brief Description of the Drawings

FIG. 1 depicts a perspective view of the dental appliance in accordance with the present invention;

FIG. 1A provides a cross-sectional view of the device of the present invention, taken across line 1-1 shown in relation to teeth positioned for immersion therein;

FIG. 2 provides a transverse cross-sectional view of the present invention as actually applied to teeth;

FIG. 3 depicts a transverse cross-sectional view of the dental appliance of the present invention which contains a buffer region;

FIG. 4 depicts a transverse cross-sectional view of the dental appliance of the present invention having an open cell foam containing a bleaching agent affixed to a anterior inner wall of the trough;

FIG. 5 illustrates a transverse cross-sectional view of the dental appliance of the present invention having a trough which is shaped such that bleaching agent is concentrated on the anterior of the teeth;

FIG. 6 illustrates a transverse cross-sectional view of the dental appliance of the present invention having a strip of open cell foam affixed along the inner front and rear walls of the dental appliance.

FIG. 7 depicts a top perspective view of the device of the present invention packaged so as to seal the bleaching agent in the dental appliance.

FIG. 7A depicts a transverse cross-sectional view of the device of the present invention wherein the packaging includes sealing the rim of the trough orifice.

FIG. 8 depicts a transverse cross-sectional view of the device of the present invention wherein premeasured bleaching agent is sealed in a container adjacent to the trough for dispensation into the dental appliance.

FIG. 8A depicts a transverse cross-sectional view of the device of the present invention wherein the premeasured bleaching agent compartment is unsealed and delivered in the reservoir cavity of the dental appliance.

Detailed Description of the Preferred Embodiments

Referring to the drawings, the device shown in FIGS. 1-2 consists of a prefabricated U-shaped dental appliance 2 having a trough along the long, horizontal axis of the dental appliance 2 containing a premeasured quantity of medicinal agent 3 for immersing the teeth 4 which are subject to treatment. The dental appliance 2 is fabricated from a non-porous polymer.

FIGS. 3-4 depict the dental appliance 2 as it appears in relation to the teeth 4 of the dental arch in actual practice. In the procedure utilized in practicing the present invention, first, an appropriate prefabricated, disposable dental appliance 2 which approximately fits around the relevant patient's dental arches is selected. The dental appliance 2 may be packaged in a preferably sterile container with a premeasured quantity of medicinal agent 3 predisposed in the trough. In accordance with the definition above, medicinal agent 3 may include a bleaching agent, such as 10 % carbamide peroxide, an antioxidant such as vitamin E, a whitening surfactant for coating the teeth such as poloaxmer, fluoride, aloe vera, a dental scrub, or any other agent for treatment of the teeth and/or the surrounding periodontal tissue.

The dental appliance 2 is next removed from the packaging and delivered to the teeth 4. Delivery of the dental appliance 2 is effected by positioning the dental appliance 2 intraorally with the trough aligned in a parallel fashion to the edges of the teeth 4 as shown in FIGS. 1A and 2. In order to correctly place the dental appliance 2 over the teeth 4, the trough is pushed in the direction of the gingiva 6 and soft tissue 8, also referred to herein as periodontal tissue, surrounding the dental arch toward and then around the edges of the teeth. Correctly placed, the dental appliance 2 covers the teeth 4 gingiva 6 of the dental arch as illustrated in FIG. 3 and provides a system whereby the dental appliance 2 delivers a premeasured quantity of medicinal agent 3 to the teeth of the dental arch in a single, simple step, after being unpackaged.

As shown in FIGS. 2, 4, and 5, teeth 4 and gingiva 6 are embedded and intimately interface with medicinal agent 3. Correct placement of dental appliance 2 results in a gingival interface formed about the orifice of the trough which facilitates localization of medicinal agent 3 within target area 5.

5 FIG. 3 depicts an embodiment of the present invention including buffer region 7 which protects against the potential untoward side effects of medicinal agent 3. Buffer region 7 may include any biocompatible agent capable of stabilizing dental bleaching or other medicinal agents such as carbamide peroxide and other peroxy compounds, e.g. antioxidants such as vitamin E, and may also include zinc oxide eugenol.
10 Buffer region 7 may further include any composition capable of minimizing potential untoward side effects of medicinal agent 3.

FIG. 4 illustrates one embodiment of the present invention wherein an open cell foam 10 is laminated or otherwise affixed to an inner wall of the dental appliance 2. The open cell foam 10 thus forms a matrix for application of the medicinal agent 3.

15 FIG. 5 depicts a preferred embodiment of the present invention wherein the dental appliance 2 is formed so that the medicinal agent 3 is confined to the anterior inner wall of the dental appliance 2 which is adjacent to target area 5 of the anterior surface of the teeth 4, when properly used. A reaction vessel is thus formed localizing medicinal agent 3 to the anterior surfaces of the teeth 4.

20 FIG. 6 illustrates an embodiment of the present invention featuring dental appliance 2 wherein a first strip of open cell foam 10' is attached along the anterior inner wall of the dental appliance and a second strip of open cell foam 10" is attached along the rear inner wall of the dental appliance such that a reservoir cavity 12 for containment of the medicinal agent is formed along the bottom of the trough of the dental appliance. In
25 this embodiment of the present invention, medicinal agent 3 is predisposed in reservoir cavity 12. When the user's teeth are placed in reservoir cavity 12, medicinal agent 3 is forced upward into open cell foam strips 10' and 10", and thus delivered to the treatment region targeted by the strips in a contained and efficient manner.

30 FIG. 7 depicts an embodiment of the present invention wherein packaging 14 envelopes the entire dental appliance 2 which contains medicinal agent 3. Alternatively, as shown in FIG. 7A, dental appliance 2 can include seal 15 of the rim of the trough of dental appliance 2 which effectuates containment of medicinal agent 3 therein.

35 FIG. 8 depicts another embodiment of the present invention wherein dental appliance 2 is encased in packaging 14'. In this embodiment, medicinal agent 3 may be contained in a separable compartment walled off by packaging 14' located adjacent to the trough of dental appliance 2. Medicinal agent 3 is sealed within the compartment by seal

15' adjoined to packaging 14' on either side of the upper surface of dental appliance 2 and by aperture seal 16, which is composed of a substantially thinner and more easily ruptured polymer substance than seal 15'. Preferably, aperture seal 16 and seal 15' are composed of polyvinyl chloride having lesser and greater densities, respectively. Application of
5 pressure on seal 15' at the rim of the orifice of the trough of dental appliance 2 or squeezing together the anterior and rear walls of dental appliance 2 triggers rupture of the easily ruptured aperture seal 16, and thereby causes expulsion of the premeasured amount of medicinal agent 3 directly into reservoir cavity 12', as illustrated in FIG. 8A.

It is to be understood that the present invention is not intended to be
10 limited to the exact details of construction, operation, exact materials or embodiments shown and described herein, as obvious modifications and equivalents will be apparent to one skilled in the art. For example, the dental appliance of the present invention could be applied to facilitate the delivery to the teeth of other therapeutic agents. This disclosure is intended to cover all alternatives, modifications, and equivalents as may be included within
15 the spirit and scope of the invention as defined by the appended claims.

The following claims represent the scope of this invention to the extent that it is subject to such delimitations. It will be appreciated by those skilled in the art that the anticipated uses and embodiments of the present invention are not amenable to precise delineation, but may vary from the exact language of the claims. Thus, the following
20 claims are drawn not only to the explicit limitations, but also to the implicit embodiments embraced by the spirit of the claims.

I claim:

1. A device for treatment of dental arches and periodontal tissue
5 which is not customized to fit individual dental arches, comprising:

(a) a dental appliance composed of a non-porous polymeric material
having a trough for immersing the teeth of the dental arch, the dental appliance being
adaptable to fit a range of variously sized dental arches;

(b) a premeasured amount of a medicinal agent predisposed within the
10 trough of the dental appliance; and

(c) a packaging means for sealing the dental appliance so as to provide
a closed, individualized single-use system for application of the medicinal agent .

2. The device of claim 1, wherein the packaging comprises a seal of
15 the orifice of the trough of the dental appliance.

3. The device of claim 1, wherein the medicinal agent which is
predisposed in a container placed within the trough of the dental appliance is placed
within a container which is sealed in a manner whereby the medicinal agent is capable of
20 being directly expelled into the trough of dental appliance when the seal is opened.

4. The device of claim 1, wherein a first strip of open cell foam is
affixed along the anterior inner wall of the dental appliance and a second strip of open cell
foam is affixed along the rear inner wall of the dental appliance such that a reservoir cavity
25 for containment of the medicinal agent is formed along the bottom of the trough of the
dental appliance.

5. The device of claim 1, wherein an open cell foam containing the
medicinal agent is affixed along the anterior portion and not the posterior portion of the
30 inner wall of the dental appliance so as to concentrate the contact area in the anterior
portion of the dental arch subject to treatment.

6. The device of claims 1, 4 or 5, wherein the anterior inner wall
surface of the trough having the open cell foam is recessed.

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7. The device of claims 1, 4, 5, 6, or 7 wherein the anterior inner wall surface of the trough is recessed along substantially the entire anterior inner wall surface of the trough of the dental appliance so as to form a treatment chamber for contacting the anterior surface of the teeth of the dental arch subject to treatment.

8. The device of claims 1, 4, 5, 6, or 7, wherein the upper portion of the inner wall or walls of the trough have an inwardly protruding lip for contact with the periodontal tissue surrounding the dental arches subject to treatment.

9. The device of claims 1, 4, 5, 6, or 7, wherein the upper portion of the inner wall or walls of the trough have an inwardly protruding lip for contact with the periodontal tissue surrounding the dental arches subject to treatment so as to form a seal between the lip and the periodontal tissue.

10. The device of claims 1, 4, 5, 6, or 7, wherein the medicinal agent comprises a bleaching agent.

11. The device of claim 10, wherein the bleaching agent comprises between about 5% and about 20% carbamide peroxide.

12. The device of claims 1, 4, 5, 6, or 7, wherein the medicinal agent comprises an antioxidant.

13. The device of claims 1, 4, 5, 6, or 7, wherein the medicinal agent comprises a bleaching agent and an antioxidant.

14. The device of claims 1, 4, 5, 6, or 7, wherein the medicinal agent comprises between about 5% and about 10% carbamide peroxide and an antioxidant.

15. The device of claims 1, 4, 5, 6, or 7, wherein the medicinal agent comprises a bleaching agent and vitamin E.

16. The device of claims 1, 4, 5, 6, or 7, wherein the medicinal agent comprises fluoride.

17. The device of claims 1, 4, 5, 6, or 7, wherein the medicinal agent comprises a bleaching agent and fluoride.

5 18. The device of claims 1, 4, 5, 6, or 7, wherein the medicinal agent comprises a surfactant for coating the surface of the teeth.

19. The device of claims 1, 4, 5, 6, or 7, wherein the medicinal agent comprises a bleaching agent and a surfactant for coating the surface of the teeth.

10 20. The device of claims 1, 4, 5, 6, or 7, wherein the medicinal agent comprises poloaxmer.

21. The device of claims 1, 4, 5, 6, or 7, wherein the medicinal agent comprises a bleaching agent and poloaxmer.

15 22. The device of claims 1, 4, 5, 6, or 7, wherein the medicinal agent comprises aloe vera.

20 23. The device of claims 1, 4, 5, 6, or 7, wherein the medicinal agent comprises a bleaching agent and aloe vera.

24. A method for treatment of dentition and periodontal tissue, comprising application of an antioxidant to the dental arches and periodontal tissue.

25 25. The method for treatment of claim 24, wherein the antioxidant comprises vitamin E.

26. The method for treatment of claim 24, further comprising simultaneously applying bleaching agent with the antioxidant.

30 27. The method for treatment of claim 26, wherein the bleaching agent comprises between about 5% and about 20% carbamide peroxide.

35 28. A method for treatment of dentition and periodontal tissue, comprising application of aloe vera to the dental arches and periodontal tissue.

29. The method for treatment of claim 28, further comprising simultaneously applying bleaching agent with the aloe vera.

5 30. The method for treatment of claim 29, wherein the bleaching agent comprises between about 5% and about 20% carbamide peroxide.

31. A method for treatment of dental arches and periodontal tissue, comprising the steps of:

10 (a) selecting a dental appliance comprising a non-porous polymeric material having a trough containing a premeasured amount of a medicinal agent predisposed within the trough of the dental appliance for immersing the teeth of the dental arch which is not customized to fit individual dental arches and is thereby adaptable to fit a range of variously sized dental arches; and

15 (b) applying the dental appliance so as to immerse a user's dental arches in the medicinal agent.

32. The method for treatment of claim 31, wherein the medicinal agent comprises a bleaching agent.

20 33. The method for treatment of claim 31, wherein the medicinal agent comprises an antioxidant.

25 34. The method for treatment of claim 31, wherein the medicinal agent comprises fluoride.

35. The method for treatment of claim 31, wherein the medicinal agent comprises a surfactant for coating the surface of the teeth.

30 36. The method for treatment of claim 31, wherein the surfactant for coating the surface of the teeth comprises poloaxmer.

37. The method of claim 31, wherein the medicinal agent comprises aloe vera.

38. The method of claim 32, wherein the medicinal agent further comprises a composition capable of minimizing untoward side effects of the bleaching agent.

5 39. A method for treatment of dental arches and periodontal tissue, comprising the steps of administering repeated treatments wherein progressively stronger concentrations of bleaching agent are applied to the dental arches and periodontal tissue.

10 40. The method for treatment of claim 39, wherein application of the progressively stronger concentration of bleaching agent comprises the steps of:

 (a) applying between about 2 and about 6 treatments of bleaching agent comprising between about 5% and about 15% carbamide peroxide;

15 (b) applying between about 2 and about 6 treatments of bleaching agent comprising between about 8% and about 18% carbamide peroxide; and

 (c) applying between about 2 and about 6 treatments of bleaching agent comprising between about 10% and about 20% carbamide peroxide.

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 41. The method for treatment of claim 39, wherein application of the progressively stronger concentration of bleaching agent comprises the steps of:

25 (a) applying between about 5 and about 10 treatments of bleaching agent comprising about 10% carbamide peroxide;

 (b) applying between about 5 and about 10 treatments of bleaching agent comprising about 12.5% carbamide peroxide; and

30 (c) applying between about 5 and about 10 treatments of bleaching agent comprising about 15% carbamide peroxide.

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 42. The method for treatment of claims 39, 40, or 41, further comprising the step of applying an antioxidant with one or more of the treatments.

43. The method for treatment of claims 39, 40, or 41, further comprising the step of applying fluoride with one or more of the treatments.

5 44. The method for treatment of claims 39, 40, or 41, further comprising the step of applying a surfactant for coating the teeth with one or more of the treatments.

45. The method for treatment of claims 39, 40, or 41 further comprising the step of applying aloe vera with one or more of the treatments.

10 46. The method for treatment of claims 39, 40, or 41, further comprising the step of applying a medicinal agent capable of minimizing potential untoward side effects of the bleaching agent with one or more of the treatments.

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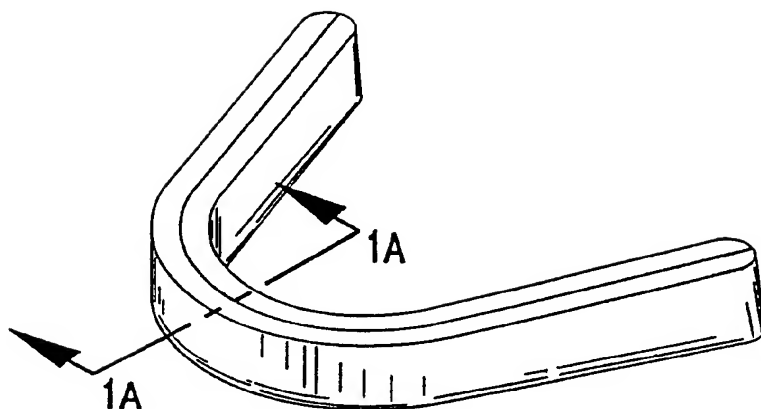


Fig. 1

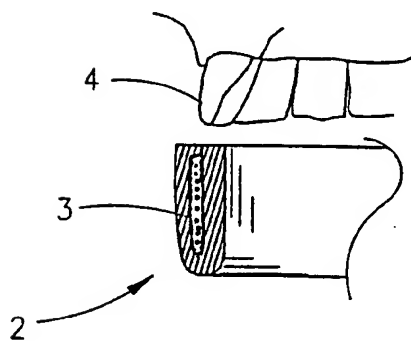


Fig. 1A

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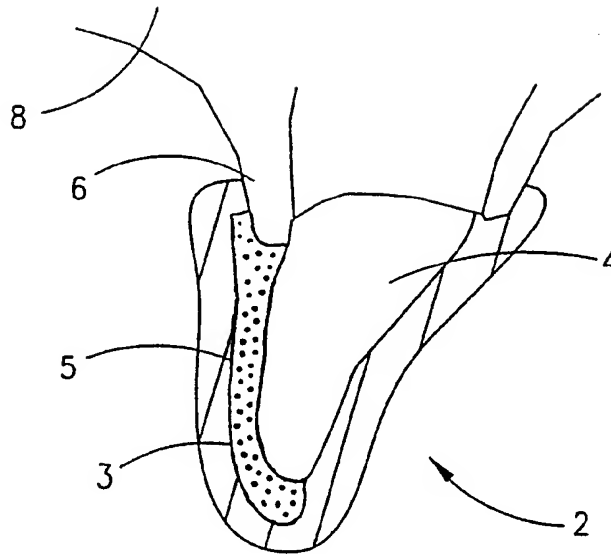


Fig. 2

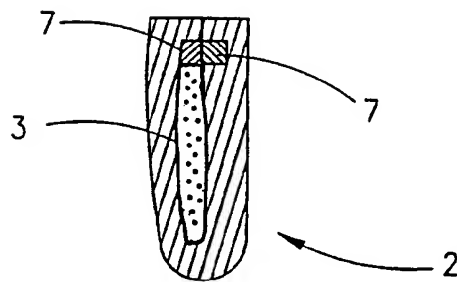


Fig. 3

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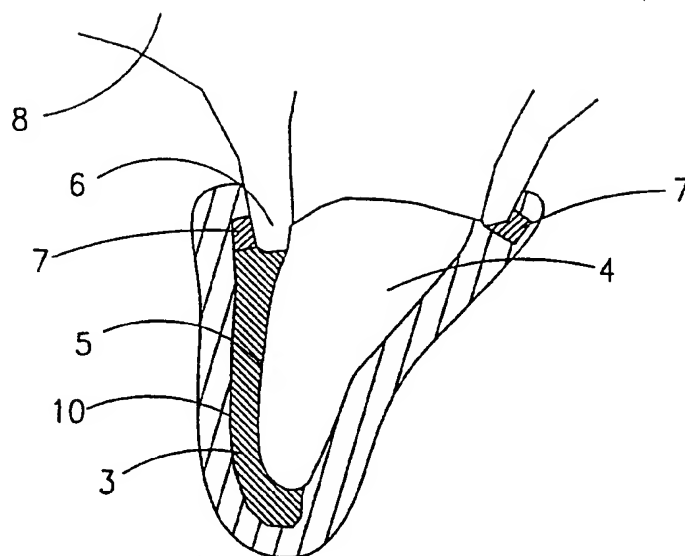


Fig.4

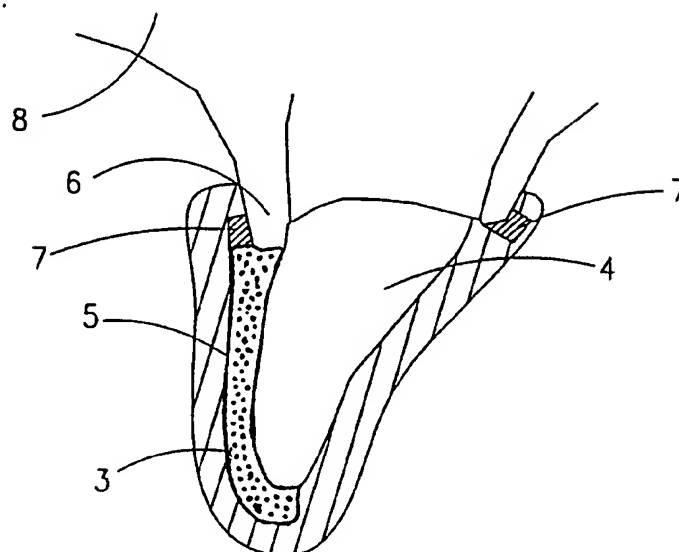


Fig.5

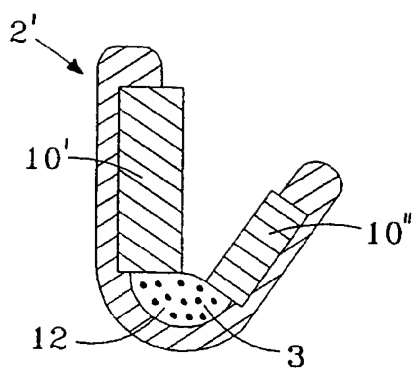


Fig. 6

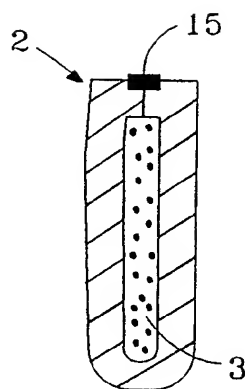


Fig. 7A

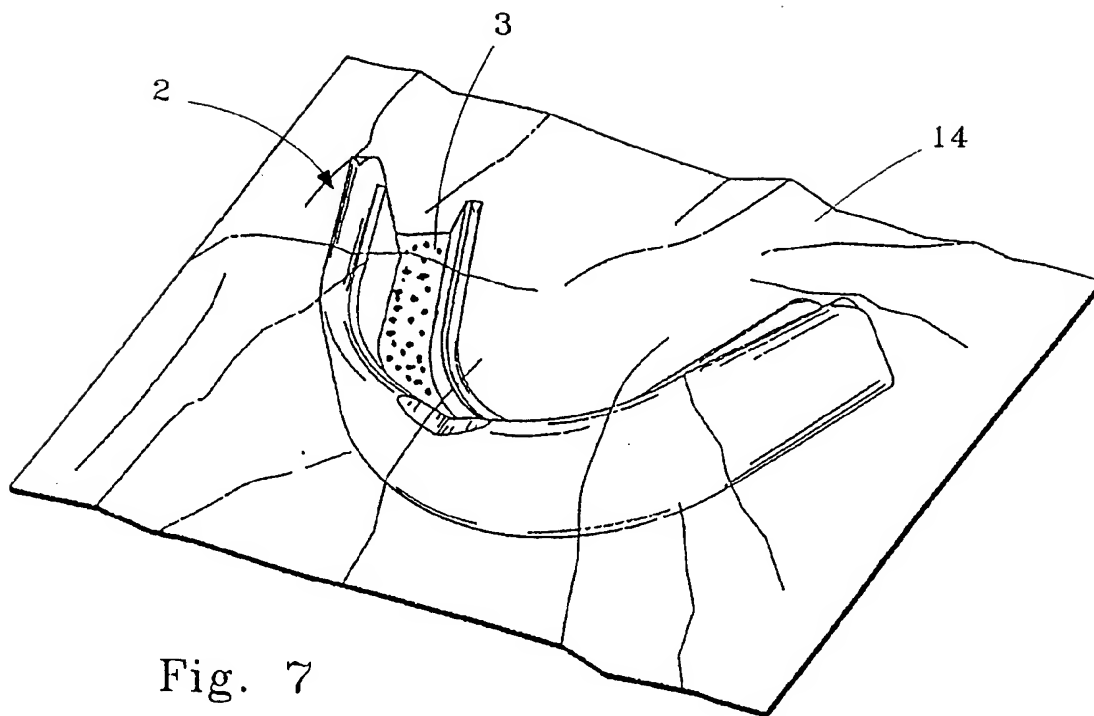
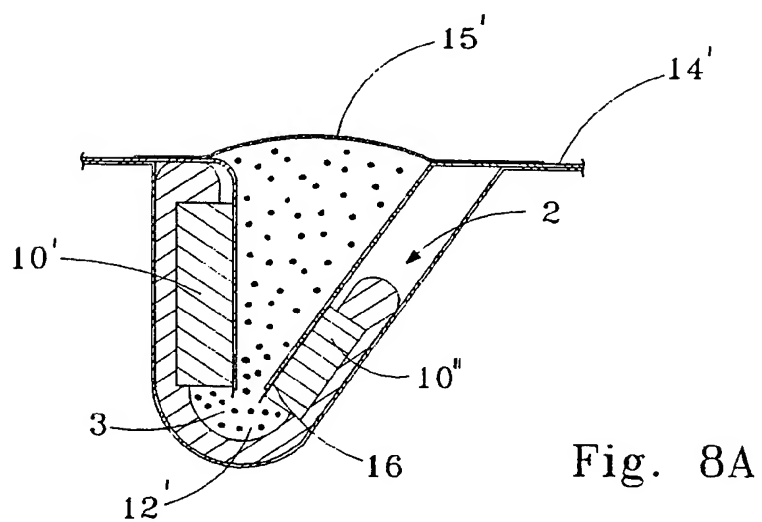
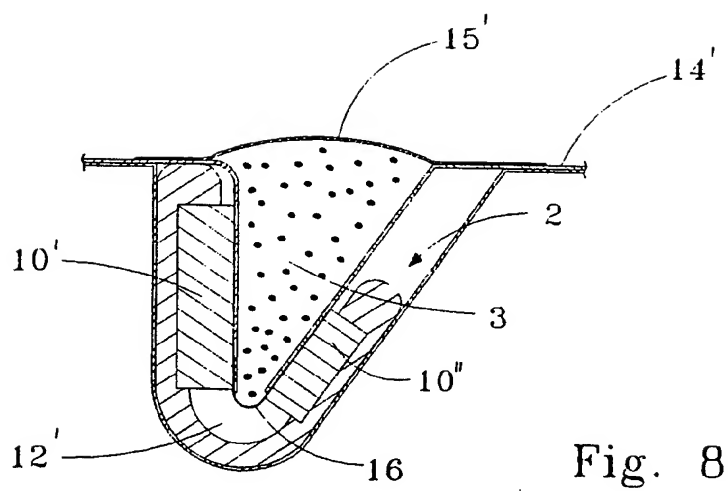


Fig. 7



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/03428

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61C 5/00

US CL :433/215

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 433/215, 216, 80; 424/53

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

search terms: bleach, aloe vera, vitamin E, antioxidant

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-------------------|---|--|
| X ---- Y | US, A, 4,226,851 (SOMPAYRAC) 07 October 1980, see column 4, lines 1-58. | 24, 25 ----- 26, 27, 33, 34, 38 |
| Y | US, A, 5,165,424 (SILVERMAN) 24 November 1992, see column 2, line 29 to column 3, line 4. | 24-30 |
| P, X ---- Y | US, A, 5,294,434 (KING ET AL.) 15 March 1994, see column 1, lines 332-38 and the abstract. | 28 ----- 29, 30, 37 |
| X ---- Y | US, A, 3,527,219 (GREENBERG) 08 September 1970, see column 1, fifth paragraph and column 1, line 57 to column 2, line 70. | 31, 32 ----- 33-35, 37, 38 |

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

| | |
|---|--|
| * Special categories of cited documents: | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| "A" document defining the general state of the art which is not considered to be part of particular relevance | "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| "E" earlier document published on or after the international filing date | "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "&" document member of the same patent family |
| "O" document referring to an oral disclosure, use, exhibition or other means | |
| "P" document published prior to the international filing date but later than the priority date claimed | |

Date of the actual completion of the international search

23 MAY 1995

Date of mailing of the international search report

26 JUN 1995

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/03428

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| Y | US, A, 4,788,052 (NG ET AL.) 29 November 1988, see column 4, lines 39-66 and column column 8, lines 3-8. | 35 |
| A | US, A, 4,990,089 (MUNRO) 05 February 1991, see entire document. | 1-6, 24-35, 37-46 |
| A, P | US, A, 5,356,291 (DARNELL) 18 October 1994, see entire document. | 1-6, 24-35, 37-46 |

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/03428

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.: 36
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

The meaning of the term "poloaxmer" cannot be determined.

3. ☒ Claims Nos.: 7-23
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.